



Accu-Chek[®] Inform II

BLOOD GLUCOSE MONITORING SYSTEM

Other Test Entry (OTE)

Supplement to the Operator's Manual

for SW 03.03.00 and higher

ACCU-CHEK[®]

| Document version | Revision date | Changes |
|------------------|---------------|---------------------------------------|
| Version 1.0 | 2011-09 | New document, created for SW 03.03.00 |

Intended use

This document provides a description of how to configure and use the *Other Test Entry (OTE)* feature of the Accu-Chek Inform II system.

It is intended as a supplement to the Accu-Chek Inform II Operator's Manual and not as a substitute for the complete manual.



Be sure to read the Accu-Chek Inform II Operator's Manual and especially the "Important safety instructions and additional information" section before using the system or performing any OTE tests.

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1 Supplement for Other Test Entry

Before you start

Description

The *Other Test Entry* feature is designed to allow the professional user to document patient test results from certain off-meter tests.

External controls are entered in the *Control Test* section. The meter facilitates the transfer of this information to a data management system (DMS).

The activation of this feature is only possible via a suitable DMS.

Activating this feature permanently adds an additional step to the *Patient Test* or a *Control Test* sequence. Once this feature is activated, you will have to select the type of test (*Glucose Test/Other Test* or *Glucose Control Test/Other Control Test*) each time.

The examples in this manual are for illustration purposes only. Consult the instructions that come with the DMS for details and configuration options.

Overview of Other Test Entry

Introduction

The *Other Test Entry* feature allows you to enter patient results for the following tests:

- Pregnancy
- Visual Urinalysis (UA)
- Rapid Streptococcus
- Rapid Drugs of Abuse Tests (DAT)
- Fecal Occult
- Gastric Occult
- Ketones

In the *Review Result* listing, the test names for the above tests will be abbreviated as follows:

- Pregnancy (Preg)
- Visual UA (VUA)
- Rapid Strep (Strep)
- Rapid DAT (DAT)
- Fecal Occult (F Occ)
- Gastric Occult (G Occ)
- Ketones (Ket)

Entering patient test results using the *Other Test Entry* menu comprises of the following steps:

- Enter the patient ID.

This can be done either manually or by using the barcode scanner.

- Enter the date and time the test was performed.
- Enter or confirm the test strip, kit and/or other reagent lot numbers.

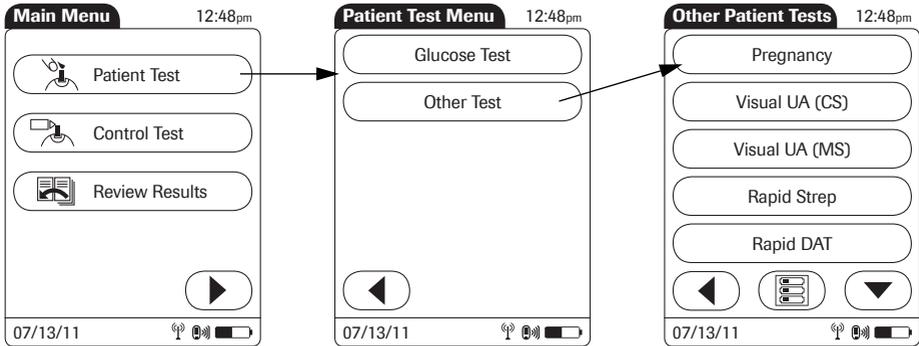
This can be done either manually or by using the barcode scanner (if a barcode is available).

- Enter the test strip, kit and/or other reagent expiration date the first time a lot number is entered.
- Enter the onboard control result(s) if available.
- Enter the test result(s).
- Select appropriate comments.

Recording Other Test Entries

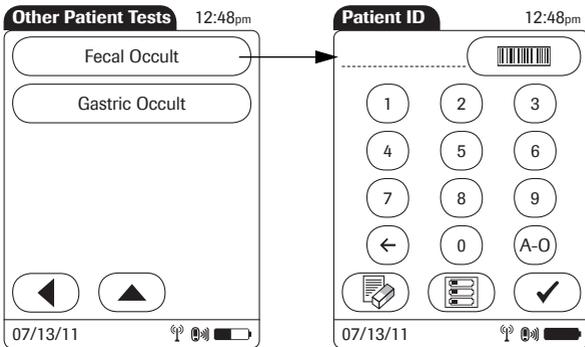
The following steps must be completed already:

- 1 The meter is powered on.
- 2 You have entered your operator ID.
- 3 You have completed login by selecting and the *Main Menu* screen is displayed.

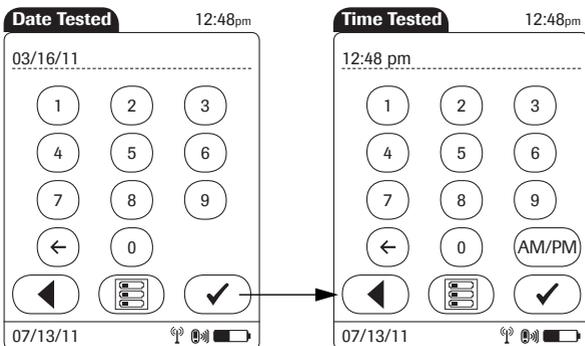


- 1 From the *Main Menu* screen touch *Patient Test*.
- 2 From the *Patient Test Menu* touch *Other Test*.
- 3 Touch or to scroll up or down in the list.
- 4 Select the desired test from the display list.

If you need to change an entry, touch to return to the previous screen.

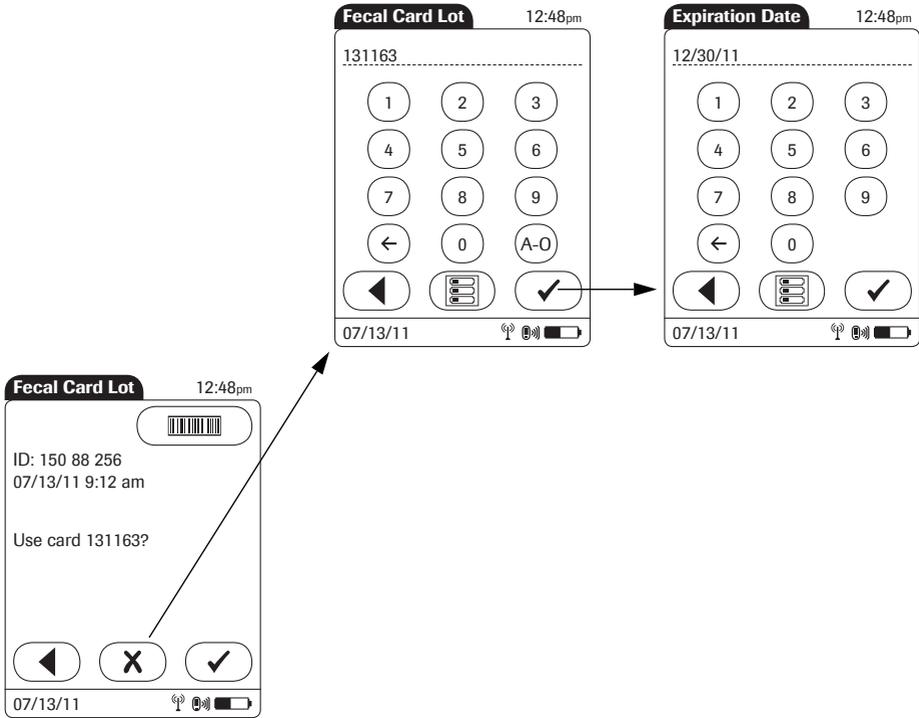


- 5 Enter or select the *Patient ID*. Touch  to proceed to the next screen¹.



- 6 Use the keypad to enter the date the test was performed. For single digit numbers, add a leading zero. Touch  to proceed to the next screen.
- 7 Use the keypad to enter the time the test was performed. For single digit numbers, add a leading zero. Touch .

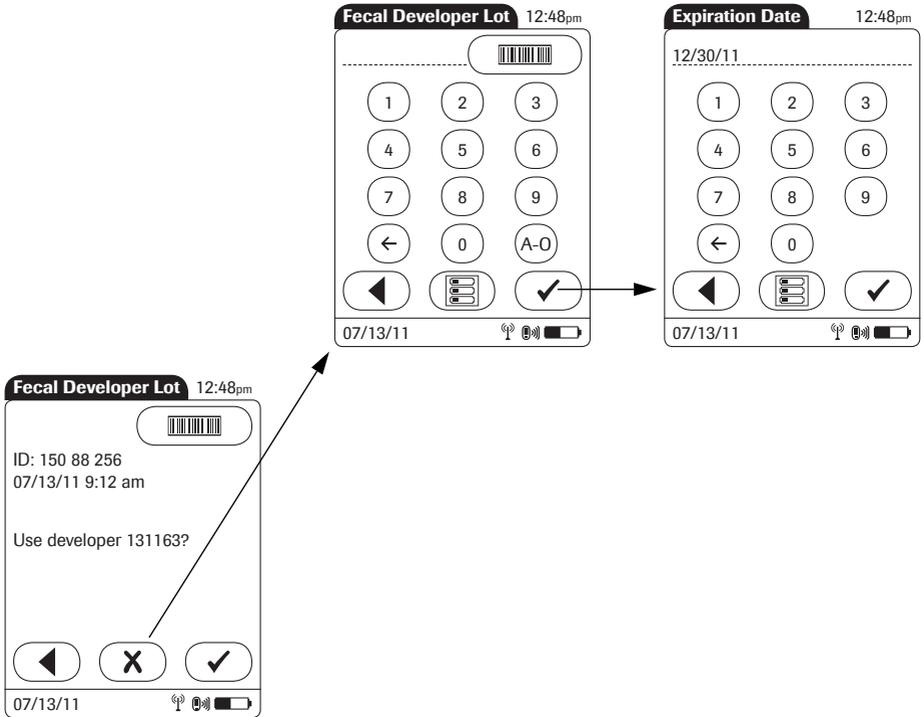
1. See also section “Entering or selecting the patient ID” in Chapter 3 of the Accu-Chek Inform II Operator’s Manual.



- 8 Use the keypad or barcode scanner to enter the *Fecal Card Lot* number, and touch to proceed to the next screen. OR, if configured:
 - Touch to confirm that you want to use the preselected lot number displayed by the meter.
 - Touch to enter a new lot number, if you want to use a different lot number than the one displayed.

If you touch to confirm the displayed lot number, the meter will not prompt for expiration date.

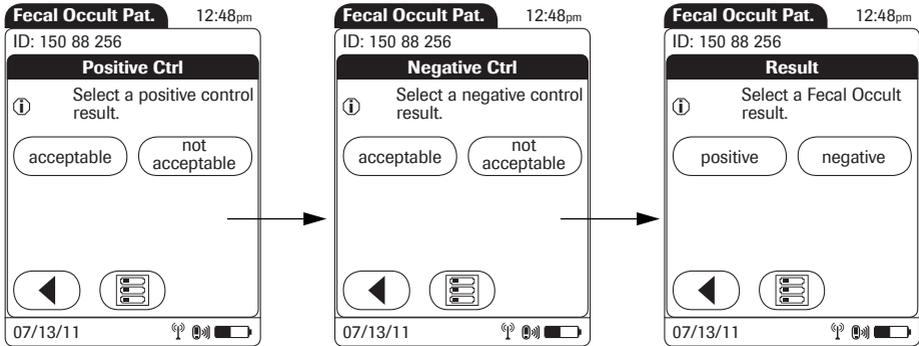
- 9 Use the keypad to enter the *Fecal Card Lot* expiration date. Touch to proceed to the next screen.



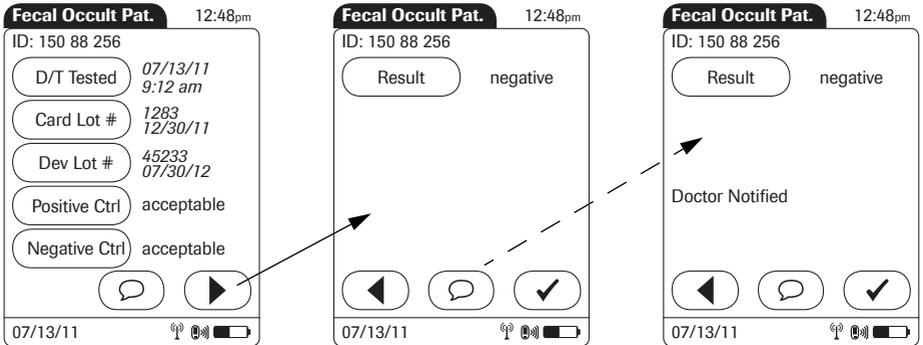
- 10 Use the keypad or the barcode scanner (if a barcode is available) to enter the *Fecal Developer Lot* number, and touch to proceed to the next screen. Or, if configured:
 - Touch to confirm that you want to use the preselected lot number displayed by the meter.
 - Touch to enter a new lot number, if you want to use a different lot number than the one displayed.

If you touch to confirm the displayed lot number, the meter will not prompt for expiration date.

- 11 Use the keypad to enter the *Fecal Developer Lot* expiration date. Touch to proceed to the next screen.



- 12 Select the result of the *Positive Control* as *acceptable* or *not acceptable* by touching the appropriate button.
- 13 Select the result of the *Negative Control* as *acceptable* or *not acceptable* by touching the appropriate button.
- 14 Select the patient test result as *positive* or *negative* by touching the appropriate button.



Once the result(s) are entered, the *Fecal Occult Pat.* result screen is displayed.

- 15 To change an entry or a result, touch the appropriate button.

To add comments¹:

- 16 In the result screen, touch .
- 17 Select the desired predefined comment from the display list (if configured) or
- 18 Touch  to enter your own custom comment. Use the keypad (as with login) to enter your comment.
- 19 Once you have selected the desired comment(s), touch .
- 20 Touch  to return to the *Main Menu*.

Test results are also saved when the meter is powered off in the results screen or automatically powers off.

1. See also section "Adding comments" in Chapter 3 of the Accu-Chek Inform II Operator's Manual.

Recording Other Control Test Entries

Introduction

The *Other Control Test Entry* feature allows you to enter liquid control results for the following tests:

- Pregnancy (Preg)
- Visual UA (VUA)
- Rapid Strep (Strep)
- Rapid DAT (DAT)

Running controls ensures that your technique used in testing will give accurate results on *Other Patient Tests*. Control solutions have defined (known) values. Commercially prepared control solutions should be used on a regular basis, as established by your institution's quality control protocols. The results for these solutions should be within a certain acceptable range in order to ensure valid other patient testing.

Other Control Testing Intervals

Intervals between running control tests are determined by your institution. Quality control lockout is not available for *Other Test Entry*.

Stored Control Information

The meter can record the following information about *Other Control Tests*:

- Operator ID
- Type of control
- Date tested
- Time tested
- Kit lot number
- Control lot number
- Control test result(s)
- Comment (if appropriate)

Entering control test results using the *Other Control Test Entry* menu comprises of the following steps:

- Select the type of control to be recorded.
- Enter the date tested (if required).
- Enter the time tested (if required).
- Enter or confirm the kit or test strip lot number.

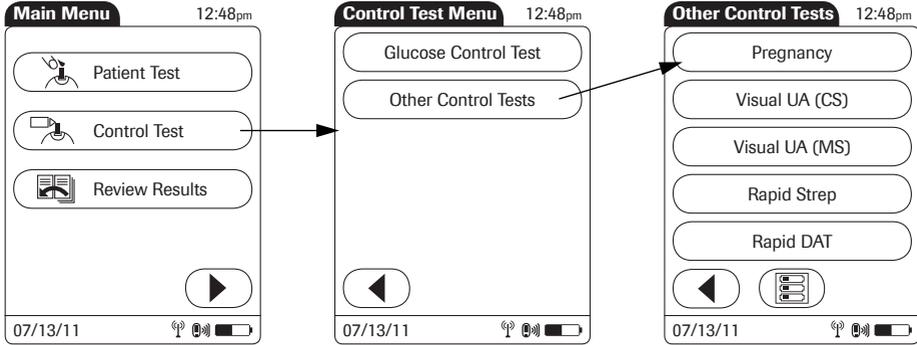
This can be done either manually or by using the barcode scanner (if a barcode is available).

- Enter the kit or test strip expiration date.
- Enter or confirm the control lot number.
- Enter the control lot expiration date.
- Select the control result(s).

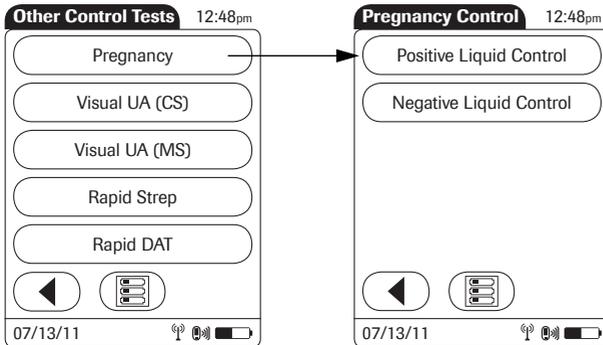
The control solution results must fall into the acceptable range indicated on the test kit or reagent packaging, or as defined by your institution, before being considered successful.

The following steps must be completed already:

- 1 The meter is powered on.
- 2 You have entered your operator ID.
- 3 You have completed login by selecting and the *Main Menu* screen is displayed.



- 1 From the *Main Menu* screen touch *Control Test*.
- 2 From the *Control Test Menu* touch *Other Control Tests*.



- 3 Select the desired test from the display list. (*Pregnancy control* will be used as an example.)
- 4 Select the type (level) of control being used.

Pregnancy Ctrl Lot 12:48pm

1 2 3

4 5 6

7 8 9

← 0 A-O

← [Menu] ✓

07/13/11 [Signal] [Wi-Fi] [Battery]

Expiration Date 12:48pm

12/30/11

1 2 3

4 5 6

7 8 9

← 0

← [Menu] ✓

07/13/11 [Signal] [Wi-Fi] [Battery]

- 5 Use the keypad or the barcode scanner (if a barcode is available) to enter the *Pregnancy Ctrl Lot* number. Touch to proceed to the next screen.
- 6 Use the keypad to enter the *Pregnancy Ctrl Lot* expiration date. Touch to proceed to the next screen.

Date Tested 12:48pm

03/16/11

1 2 3

4 5 6

7 8 9

← 0

← [Menu] ✓

07/13/11 [Signal] [Wi-Fi] [Battery]

Time Tested 12:48pm

12:48 pm

1 2 3

4 5 6

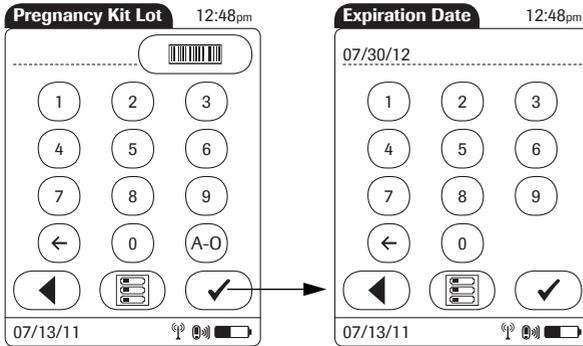
7 8 9

← 0 AM/PM

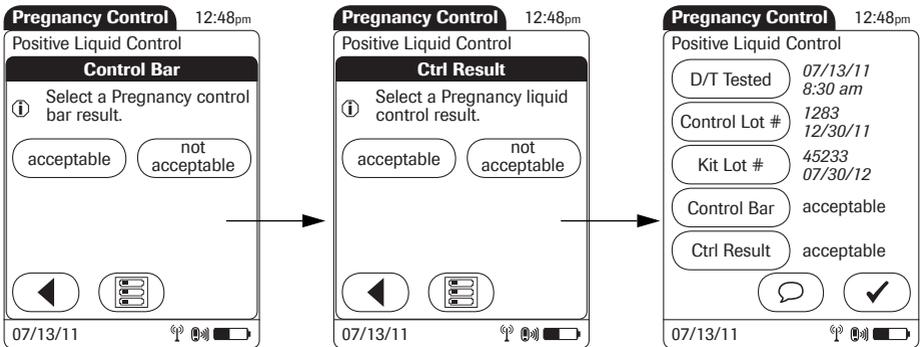
← [Menu] ✓

07/13/11 [Signal] [Wi-Fi] [Battery]

- 7 Use the keypad to enter the date the test was performed. For single digit numbers, add a leading zero. Touch to proceed to the next screen.
- 8 Use the keypad to enter the time the test was performed. For single digit numbers, add a leading zero. Touch to proceed to the next screen.



- 9 Use the keypad or the barcode scanner (if a barcode is available) to enter the *Pregnancy Kit Lot* number. Touch to proceed to the next screen.
- 10 Use the keypad to enter the *Pregnancy Kit Lot* expiration date. Touch to proceed to the next screen.



- 11 Select the result of the *Control bar* test as *acceptable* or *not acceptable* by touching the appropriate button.
- 12 Select the result of the liquid control test (*Ctrl Result*) as *acceptable* or *not acceptable* by touching the appropriate button.

Once the results are entered, the *Pregnancy Control* result screen is displayed.

- 13 To change an entry or a result, touch the appropriate button.

To add comments¹:

- 14 In the result screen, touch .
- 15 Select the desired predefined comment(s) from the display list (if configured) or
- 16 Touch  to enter your own custom comment(s). Use the keypad (as with login) to enter your comment.
- 17 Once you have selected the desired comment(s), touch  to return to the results screen.
- 18 Touch  to return to the *Main Menu*.

Test results are also saved when the meter is powered off in the results screen or automatically powers off.

1. See also section "Adding comments" in Chapter 3 of the Accu-Chek Inform II Operator's Manual.

Warning messages

The meter may display error or warning messages when you enter *Other Patient Tests* and *Other Control Tests*. These error or warning messages occur when the validity of the recorded result is questionable. These messages caution that test information may not be valid or accurate. (See also “Error Messages” in Chapter 10 of the Accu-Chek Inform II Operator's Manual.)

When entering other patient and other control test results, the user may be prompted to enter a control test (control bar) result as either acceptable or not acceptable. If the result is entered as not acceptable, subsequent patient results may not be valid due to the invalid control bar result.

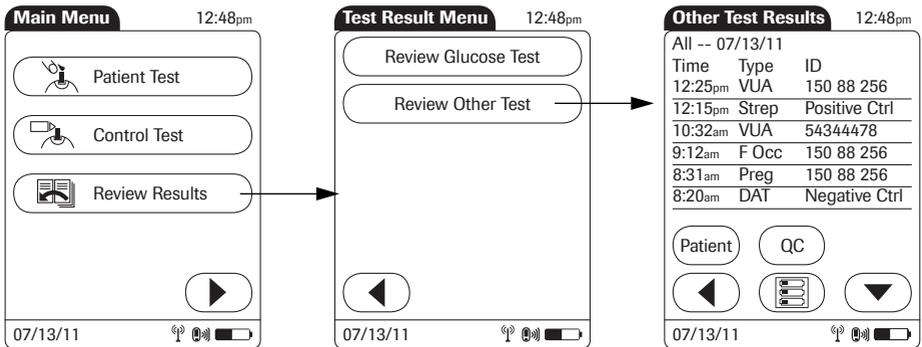
Reviewing Results for Other Test Entry

The *Other Test Result* screen displays all stored OTE results. Results can be viewed in three ways: *All*, *Patient*, or *QC*.

The following steps must be completed already:

- 1 The meter is powered on.
- 2 You have entered your operator ID.
- 3 You have completed login by selecting and the *Main Menu* screen is displayed.

Perform the following steps to *Review Other Test* result(s):



- 1 From the *Main Menu* screen touch *Review Results*.
- 2 From the *Test Result Menu* touch *Review Other Test*.

All stored OTE test results are displayed in a sequential list.

Other Test Results 12:48pm

All -- 07/13/11

| Time | Type | ID |
|---------|-------|---------------|
| 12:25pm | VUA | 150 88 256 |
| 12:15pm | Strep | Positive Ctrl |
| 10:32am | VUA | 54344478 |
| 9:12am | F Occ | 150 88 256 |
| 8:31am | Preg | 150 88 256 |
| 8:20am | DAT | Negative Ctrl |

Patient QC

◀ ☰ ▼

07/13/11   

Fecal Occult Pat. 12:48pm

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ID: 150 88 256
 Name: Helen Schneider
 07/13/11 9:12 am
 Card Lot # 1283
 12/30/11
 Dev Lot # 45233
 07/30/11

Patient QC ▲

◀ ☰ ▼

07/13/11   

Fecal Occult Pat. 12:48pm

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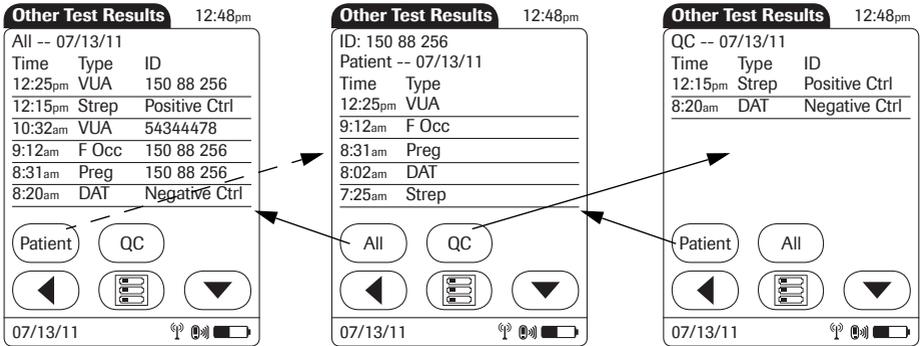
ID: 150 88 256
 Positive Ctrl acceptable
 Negative Ctrl acceptable
 Result negative
 Doctor Notified

Patient QC ▲

◀ ☰ ▼

07/13/11   

- 3 Touch ▲ or ▼ to scroll up or down in the list. The results are grouped by date.
- 4 Touch an entry in the list to display the related details.
- 5 Touch ▲ or ▼ to display all available pages of a test result.



- 6 Touch *Patient*, if you wish to display results for a specific patient only.
 - If you touch *Patient* from the full list view, you will be asked to enter the patient ID manually or via barcode scanner. The list now contains only the results for the selected patient.
- 7 Touch *QC*, if you wish to display a list of other control tests.
- 8 Touch *All* in the *Other Test Results* screen to remove the *Patient* or *QC* selection and display all results.
- 9 Touch ◀ to return to the previous menu screen, or
- 10 Touch ☰ to return to the *Main Menu*.

Other Test Entry Configuration Options

Other Test Entry options can only be configured using a DMS. The availability of electronic configuration options will thus vary according to the data management software utilized by your institution. Consult your system administrator.

The OTE feature is enabled or disabled by the configuration option listed below. See the Accu-Chek Inform II Operator's Manual for a complete list of other configuration options.

Configuration options

| Subject/Attribute | Range | Default | Device | DMS |
|--------------------------------------|---------------------------|---------|--------|-----|
| Other Test Entry (OTE) | | | | |
| OTE functionality * | 0: disabled 1: enabled | 0 | N | Y |
| * Depends on available DMS settings. | | | | |



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